IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL 2327**
THIS DOCUMENT RELATES TO ETHICON WAVE 1 CASES	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

MEMORANDUM IN SUPPORT OF PLAINTIFFS' MOTION TO EXCLUDE THE GENERAL CAUSATION OPINIONS OF BRIAN J. FLYNN, MD

Plaintiffs submit this brief in support of their Motion to Exclude the General Causation Opinions of Brian Flynn, M.D., as it relates to the cases set forth on Exhibit A to Plaintiffs' accompanying Motion.

INTRODUCTION

Dr. Flynn is a urologist in Colorado with experience in the treatment of stress urinary incontinence ("SUI") and pelvic organ prolapse ("POP"), as well as the removal of POP and sling systems. Dr. Flynn intends to provide general opinions about: TVT, TVT-O, TVT-Secur, used to treat SUI, as well as Prolift and Prolift+M, used to treat POP.[1] As discussed below, the Court should exclude Dr. Flynn's opinions because: (1) he admits he is not qualified to offer a number of opinions; (2) he failed to review much of the relevant literature; (3) he failed to review literature that was inconsistent with his opinions; and (4) he offers impermissible legal opinions and broad unsubstantiated statements that are not the proper subject of expert testimony. As Dr. Flynn's opinions are not the product of a reliable methodology and exceed his qualifications, his testimony should be excluded.

LEGAL STANDARD

[1] *See* TVT Report (attached as Exhibit B), TVT-O Report (attached as Exhibit C), TVT-S Report (attached as Exhibit D), Prolift Report (attached as Exhibit E), Prolift+M Report (attached as Exhibit F).

In addition to specific legal citations and argument contained in this Memorandum, Plaintiffs incorporate by reference the standard of review for *Daubert* motions set forth by this Court in *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 692, 701 (S.D. W. Va. 2014).

I. THE COURT SHOULD EXCLUDE DR. FLYNN'S OPINIONS BECAUSE THEY ARE NOT THE PRODUCT OF ANY RELIABLE METHODOLOGY.

Dr. Flynn worked for Ethicon as a consultant from 2004 at least through 2011. According to an email he wrote in 2011, Dr. Flynn then began working to "help defend J&J in a class action…" Flynn 4/19/16 22:12-23 (attached as Exhibit G). He has continued to work as an expert witness for Ethicon until today. That is, for over a decade, Dr. Flynn has been paid by Ethicon.

In all five of his expert reports, Dr. Flynn states that he reached his opinions on two primary grounds: (1) his review of the medical literature; and, (2) his personal experience. *See, e.g.*, TVT Report at 1. However, merely pronouncing that one has followed these "methods" is insufficient to pass *Daubert* muster. As discussed below, Dr. Flynn's medical literature review was, at best, sporadic, incomplete, and limited to literature that supported his predetermined opinions. Moreover, his "personal experience" is not based on any systematic review of his treatment and practice – it is, instead, an ad hoc gut feeling filled with unsupported assumptions and "guesses" that are unscientific and impossible to test or investigate.

Accordingly, because Dr. Flynn cannot support his opinions with any reliable scientific methodology, his opinions should be excluded in their entirety.

A. Dr. Flynn Failed to Employ A Reliable Methodology When Reviewing the Medical Literature and Science.

An acceptable scientific method requires that an expert reach opinions based on a reasoned analysis of the entire body of scientific evidence. Here, Dr. Flynn admits that he: (1) failed to perform a systematic review of all of the literature; (2) only included literature in his

reports that supported his predetermined opinions; and, (3) ignored the substantial evidence that was contrary to his opinions. Absent a thorough and systematic review of the totality of scientific literature, including a discussion of contrary evidence, an expert's opinions are not grounded in a reliable methodology and should be excluded.

As this Court has stressed, an expert's opinion is the result of an unreliable methodology if the expert "fails to account for contrary scientific literature and instead selectively [chooses] his support from the scientific landscape." *Eghnayem v. Boston Scientific Corp.*, 57 F. Supp. 3d 658, 676 (S.D. W. Va. 2014) (internal citation and quotation omitted); *See also Sanchez v. Boston Scientific Corp.*, 2:12-cv-05762, 2014 WL 4851989, at *12-13 (S.D. W. Va. Sept. 29, 2014) (excluding expert opinion for failure to explain contrary evidence) *see also Barber v. United Airlines, Inc.*, 17 F. App'x 433, 437 (7th Cir. 2001) (explaining that where an expert "cherry-picked the facts he considered to render an expert opinion … such a selective use of facts fails to satisfy the scientific method and *Daubert*.").

Here, Dr. Flynn admitted that he did not perform a systematic review of the relevant scientific literature. In fact, when asked how he chose the literature to review and rely upon, Dr. Flynn could not articulate any method supporting his review. For example, during his deposition regarding Prolift when asked how he chose which literature to review and analyze, Dr. Flynn testified as follows: "It's not a systematic review. That's correct." Flynn 4/14/16 11:52 A.M. 26:18-19 (attached as Exhibit H). He further agreed that he did not have any type of systematic approach to his literature search for his reports. *Id.* at 60:3-12.

Instead of a systematic review, Dr. Flynn admitted that he purposely cherry-picked favorable evidence to review and analyze. He testified as follows: "I tried to choose articles that supported my opinions, so it's more what I use to make my opinions, not what I decided not to

use." *Id.* at 24:13-15. When asked if he intentionally chose not to cite or discuss studies that were contrary to his opinion, Dr. Flynn further testified, "There's articles that I'm aware of that I did not cite in this report … the articles that I cite are articles that I feel are valuable and supportive of my opinions." *Id.* at 25:14-22.

When presented with a number of studies that he chose not to discuss in his report and that reached contrary conclusions, he was unable to explain why he disregarded that evidence. When asked if those studies met his inclusion criteria, he admitted, "I would have to look at them more specifically. I didn't have time to look at those. They may have, they may not have." *Id.* at 223:6-224:1.

Beyond not having enough time, Dr. Flynn is apparently so entrenched in his opinions that he did not even want to review all the relevant literature. For example, after being confronted with contrary evidence that he did not review or discuss in his reports, Dr. Flynn stated, "I believe I've read enough articles on degradation. I've read enough systematic reviews and meta-analyses to feel confident in my opinion." Flynn 4/19/16 75:25-76:7. In another example, he was asked if he reviewed all the relevant Prolift literature and responded, "I reviewed enough information to stand behind my opinions in this report." Flynn 4/14/16 11:52 A.M. 178:1-6. Under *Daubert* and Rule 702, "I've read enough" is simply not reliable.

Additionally, Dr. Flynn has testified that he doubts anything could change his opinions. When asked if there is anything in the medical literature that he has *not reviewed* that could possibly change his opinions, he admitted, "There's always possibilities, but I think it's unlikely." *Id.* at 178:16-20. Dr. Flynn even testified that his opinion would not be affected if the FDA had reviewed all the studies he relied upon and concluded that there was still insufficient evidence to establish the safety and efficacy of Prolift. *Id.* at 85:1-21. Dr. Flynn's opinions are

not the product of a sound scientific methodology – they are instead the unfounded opinions of a physician who has effectively been employed by Ethicon for nearly a dozen years.

Plaintiffs will not discuss every piece of evidence that Dr. Flynn either completely missed or intentionally disregarded because it did not support his preconceived conclusions. Such a review would unduly burden the Court and is largely unnecessary because, as noted above, Dr. Flynn admitted that cherry-picking was his chosen methodology. However, what follows are several examples that illustrate Dr. Flynn's unabashed refusal to follow a reliable methodology.

1. Dr. Flynn overlooked or consciously ignored the best evidence regarding the safety of the TVT-Secur.

In his TVT-Secur report, Dr. Flynn opined that the TVT-Secur single incision sling was as safe and efficacious as any other sling for treatment of SUI. TVT-S Report at 24-7. To support his opinions, Dr. Flynn relied heavily on a systematic review from the Cochrane Collaboration. TVT-S Report at 22. Dr. Flynn testified that reviews such as this Cochrane Review, are, in his opinion, one of the highest levels of evidence. He testified as follows: "I think the Cochrane reviews, systematic reviews are very powerful, so it's level one evidence, yes." Flynn 3/24/16 10:29 A.M. 69:5-7 (attached as Exhibit I).

However, the Cochrane Review upon which Dr. Flynn relied only studied multi-incision, full length slings, such as the TVT-R and TVT-O. In fact, the Cochrane Review upon which Dr. Flynn relied did not mention the TVT-Secur. Flynn 3/24/16 68:16-69:14; TVT-S Report at 22 ("While not specifically applicable to single-incision slings like the TVT-Secur…"). Yet, it was this "very powerful" "level one evidence" upon which he based his opinion that the TVT-Secur single incision sling was safe and efficacious.

During his deposition regarding the TVT-Secur product, Dr. Flynn was presented with a different systematic review from the Cochrane Collaboration – a paper entitled, "Single Incision

Sling Operations for Urinary Incontinence in Women." This Cochrane Review, also "very powerful" "level one evidence," specifically reported on single incision slings, and, in fact, primarily studied the TVT-Secur. The review noted that the TVT-Secur was "withdrawn from the market because of poor results." Flynn 3/24/16 10:29 A.M. 72:7-11. Specifically, the study noted that women were more likely to remain incontinent after surgery with single-incision slings as compared to other mesh devices. *Id.* at 72:19-24. The study concluded that the TVT-Secur "adverse event profile was significantly worse, especially consisting of higher risks of vaginal mesh exposure, bladder/urethral erosion and operative blood loss …" *Id.* at 75:20-76:2.

When asked if he had even seen this systematic review, Dr. Flynn answered, "I don't believe so." *Id.* at 70:8-11. When asked why he had never seen this "level one evidence" that completely contradicted his opinions, he had no answer. *Id.* at 69:15-20. Likewise, he offered no explanation for why he instead chose to rely upon a Cochrane Review concerning completely different devices. Amazingly, he testified that he did not believe it would be more reliable to rely upon the Cochrane Review actually discussing the TVT-Secur when analyzing the safety and efficacy of the TVT-Secur. *Id.* at 70:24-71:5. Without explanation, he testified that he simply disagreed with the paper's conclusion. *Id.* at 75:20-76:14.

In sum, Dr. Flynn failed to review what he described as "very powerful" "level one evidence" regarding the TVT-Secur because he did not perform a reliable or systematic review of the relevant scientific literature. As a result of this methodological flaw, Dr. Flynn completely missed (or intentionally excluded) what he claims is the highest level of evidence concerning the safety and efficacy of the TVT-Secur. When confronted with this high level evidence, Dr. Flynn could not explain why he failed to discuss it in his report; nor could he identify any sound scientific reason to explain the contradictions between his opinions and this "level one

evidence." Dr. Flynn's haphazard review of the relevant scientific literature undermines the reliability of his opinions that the TVT-Secur is safe and effective, and they should be excluded.

2. Dr. Flynn Ignored Evidence Demonstrating the TVT-O Was Associated With an Increased Risk of Nerve Injury.

This same failure to systematically review the scientific literature infects all of Dr. Flynn's reports and all of his opinions. For example, in his TVT-O report, Dr. Flynn opines that the TVT-O is a safe and effective treatment option for women suffering from SUI. However, in his deposition regarding the TVT-O, he testified that he no longer uses the TVT-O and, in fact, has not used one in years because, in his opinion, the TVT-Abbrevo is a better product. He testified as follows: "Sitting here today with the information and experience I had with both products, no, there'd be no reason I would use a TVT-O over the TVT-Abbrevo unless the patient had requested that." Flynn 4/14/16 8:42 A.M. 44:3-6 (attached as Exhibit J). Of course, this admission brings into question how he reached the conclusion in his report that the TVT-O is an appropriate choice for patients. Again, it is evident Dr. Flynn reached this conclusion because that is what Ethicon asked him to do, not based upon any reliable review of the science nor his own experience.

In his report, Dr. Flynn opines that the TVT-O is safer than other obturator devices because the "inside-out" approach of the TVT-O "allows a greater distance between the implanted mesh and the obturator nerve, thereby reducing potential complications in SUI surgery." TVT-O Report at 21. When asked for scientific support for this statement, Dr. Flynn could not provide any, other than saying that was "his experience." He did, however, agree that "if the TVT-Obturator actually came closer to the obturator bundle, it could increase the risk of nerve pain and nerve damage." Flynn 4/14/16 8:42 A.M. 54:20-25. He further admitted that there would only be an increased risk of nerve damage if the TVT-O difference in proximity to

the nerve bundle was closer both "statistically significant[ly] as well as clinically significant[ly]." *Id.* at 57:5-14.

Dr. Flynn was then shown numerous scientific papers – papers he had failed to find or discuss because he did not perform a systematic review – that all demonstrated that the TVT-O passed closer to the nerve bundle than other obturator slings – and the difference was both statistically and clinically significant. For example, he was shown the *Zahn* study which demonstrated that the TVT-O is statistically significantly closer to the nerve bundle as compared to other obturator devices. *Id.* at 58:20-60:14. Specifically, the study found that the TVT-O was 1 centimeter closer, a distance and Dr. Flynn admitted was clinically significant -- "Clinically, 1 centimeter is a big difference, yes, in surgery." *Id.* at 60:5-14.

Dr. Flynn was also shown the *Achtari* study which concluded that, of all obturator devices, the TVT-O was the closest to the obturator canal. *Id.* at 60:15-61:7. Additionally, Dr. Flynn was shown the *Spinosa* study which concluded that the TVT-O put patients at a greater risk of nerve injury because the device was placed closer to the nerve bundle. *Id.* at 61:8-62:14. Dr. Flynn admitted that these three studies concluded that the TVT-O was closer to the obturator nerve bundle than other obturator devices and that this could increase the risk of nerve damage and pain. *Id.* at 63:3-5. Hence, not only did Dr. Flynn have no support for his opinion that the TVT-O was safer than other obturator devices, his opinion was directly contradicted by the scientific literature – literature that he never found or never reviewed.

Dr. Flynn could not have reliably assessed the risk benefit profile of the TVT-O device if he failed to review the relevant literature showing that the TVT-O put patients at a greater risk of nerve damage and nerve pain. His opinions about the safety of the TVT-O should be excluded.

3. Dr. Flynn Ignored Important Evidence Regarding the Prolift and Prolift+M Products.

Dr. Flynn opines that mesh-based repairs for prolapse such as Prolift and Prolift+M are significantly more efficacious than native tissue repairs. In support of this proposition, he cites to the 2013 Cochrane Review by *Maher*. Prolift Report at 8; Prolift+M Report at 9; Flynn 4/14/16 11:52 A.M. 91:1-8. However, in a replay of his TVT-Secur opinions, Dr. Flynn fails to discuss the updated Cochrane Review that was published in 2016 – before Dr. Flynn issued these reports. Importantly, the updated 2016 Cochrane Review concluded that the use of transvaginal mesh products to treat prolapse, like the Prolift and Prolift+M, is associated with higher rates of reoperation, bladder injury, and de novo stress urinary incontinence. 4/14/16 11:52 A.M. 218:15-25. The 2016 Cochrane Review specifically concluded, "The risk-benefit profile means that transvaginal mesh has limited utility in primary surgery." *Id.* at 222:8-12.

During his deposition, Dr. Flynn testified that he was "aware" of the updated review. *Id.* at 171:15-17. When asked if he knew whether the update included additional studies that were not included in the outdated 2013 Review, he responded, "I don't know the answer to that." When asked if the 2016 Review included nine studies that were also not included in his reliance materials, he responded, "I wasn't aware of that." *Id.* at 175:13-20. Consistent with his entrenched, non-scientific methods and without actually reviewing the studies, Dr. Flynn again insisted that none of the nine additional studies would affect his opinions here. *Id.* at 178:21-179:1. When asked if he would have liked an opportunity to adequately review the updated 2016 Cochrane Review before reaching his opinions, he responded that he had reviewed *enough* information. He testified as follows: "Not necessarily. I feel that I had a wealth of information on a product that was well studied." *Id.* at 175:6-12. Dr. Flynn also testified that regardless of any contrary evidence, his opinions will not change, "I don't think it's going to change my opinions very much, no." *Id.* at 175:1-5.

As with the TVT-Secur, the conclusions of the updated POP Cochrane Review were completely contrary to Dr. Flynn's opinions. Like with the TVT-Secur, Dr. Flynn simply disagreed with the conclusions from this "very powerful" evidence without explication or analysis – in fact, without even reading the relevant studies. *Id.* at 222:8-12. Instead, he chose to rely on the earlier, outdated Cochrane Review – the one that reviewed fewer studies, but supported his opinions. *Id.* at 219:5-18. Dr. Flynn similarly disregarded or ignored numerous other scientific papers that were contrary to his predetermined opinions.

Included on his reliance list but not discussed in his report is a 2012 study by *Stanford* from the *International Urogynecology Journal*. *See* Reliance List (attached as Exhibit K). Dr. Flynn admitted that he was "more familiar" with other studies, but agreed the study was from a respectable peer-reviewed journal, one in which he publishes. Flynn 4/14/16 11:52 A.M. 102:13-103:6. Dr. Flynn testified that he disagreed with the authors' conclusion that native tissue repairs were as efficacious as mesh based repairs in treating pelvic organ prolapse. *Id.* at 103:20-104:7. He acknowledged that he did not discuss this contrary evidence in his report and had not provided any explanation for why he disagreed with its findings. *Id.* at 104:8-13. When asked whether he thought the study was reliable, he admitted, "I don't have an opinion. I'm not that familiar with this study." *Id.* at 104:19-22. Instead, the only explanation Dr. Flynn provided for refusing to review or rely on this study was that he cited other evidence that supported his opinions, including the outdated "Cochrane review [which] has a contrary result." *Id.* at 105:1-6.

Dr. Flynn then testified that his opinions in his report would not be affected if the updated Cochrane Review had reached a conclusion consistent with the Stanford findings – specifically that native tissue repair is as efficacious as mesh-augmented repairs such as the Prolift product. *Id.* at 105:17-23. Dr. Flynn's selective reliance on only favorable evidence and acknowledgment

that his opinions would not change if that evidence he relied upon reached a contrary conclusion again demonstrates he did not follow a reliable methodology in reviewing the medical literature.

Another study included on his reliance list but not discussed in his report is the 2010 randomized control trial by *Iglesia*. The *Iglesia* study concluded that mesh-based prolapse kits, like the Prolift and Prolift+M, were associated with a high vaginal mesh erosion rate with no difference in overall objective and subjective cure rates as compared to native tissue repair. *Id.* at 110:5-21. Dr. Flynn admitted that this study's conclusions were "contrary to some of [his] opinions" and that he did not discuss the study or any of its conclusions in either his Prolift or Prolift+M report. *Id.* at 110:17-111:14.

A third study that was cited on his reliance list but not discussed in his report is a 2009 study by Dr. Diwadkar from the journal *Obstetrics and Gynecology*. That study concluded that the "rate of complications requiring reoperation and the total reoperation rate was highest for vaginal mesh kits [like Prolift and Prolift+M].…" *Id.* at 112:2-10. Dr. Flynn acknowledged he did not have "much familiarity with this study" and he agreed that the study's conclusions were contrary to his opinions. Despite being unable to provide any criticisms of the study, he again admitted that the contrary evidence did not affect his opinions. *Id.* at 111:23-112:13.

In sum, all of Dr. Flynn's reports are based on his review of the scientific literature. However, by his own admission, he did not perform a systematic review or search to identify that literature. As noted above, this often resulted in Dr. Flynn relying on outdated, incorrect science. In addition, Dr. Flynn testified that he intentionally chose and reviewed literature that supported his predetermined opinions and did not analyze or discuss scientific literature that contradicted his opinions – that is, he admittedly cherry picked. In fact, when confronted with scientific literature that directly contradicted his opinions – even when that literature was merely an update

of literature he did rely upon – he refused to even allow for the fact that it might alter his opinions. To the extent Dr. Flynn's opinions are based on his review of the scientific literature, they are completely unreliable. Finally, Dr. Flynn's refusals to even consider sound scientific evidence that contradicts his predetermined opinions demonstrates his methods are results-driven and not the product of a reasoned scientific analysis. Dr. Flynn's opinions should be excluded.

B. DR. FLYNN HAS NOT DISCLOSED ANY RELIABLE METHODOLOGY SUPPORTING HIS OPINIONS BASED ON HIS PERSONAL EXPERIENCE.

In addition to his "literature review," Dr. Flynn insists that he reached his opinions based on his "personal experience." However, other than generalized, unverifiable "trust me" statements regarding his personal experience, he has not shown that his reporting of his personal experience is based on any reliable scientific method.

As an initial matter, Dr. Flynn's recollection of his personal experience is ever-changing. For example, on March 24, 2016, he testified, "I started doing the TVT Obturator later in my practice … after the [TVT] retropubic." Flynn 3/24/16 10:29 A.M. 35:24-36:1. A month later, he testified differently, "The first product I used was TVT-Obturator. That was in 2004. Sometime after that I used the TVT classic device." Flynn 4/19/16 34:21-22. When asked how many Ethicon products he has implanted, he had to guess. When asked how many of his patients experienced complications, he could not answer because he has not reviewed his patient files. He further testified that he has not performed any type of formal review of the patients he has treated for complications. Flynn 4/14/16 11:52 A.M. 27:3-22. He admitted that he did not actually know how many of his patients he saw at two years or how many were loss to follow up. Flynn 4/19/16 103:8-105-10. When asked how many patients were lost to follow up, he guessed the number was less than 5 percent and admitted "[t]hat's an approximation." Id. at 104:22-105:1. When asked the basis for that guess, he stated that was based on his review of other

studies. Extrapolating his personal experiences from the statistical percentages from other studies is hardly scientific.

Regarding revision surgeries he has performed, Dr. Flynn admitted that he does not keep track of the product he is explanting and that most of the time he does not even know what the product is. Flynn 3/24/16 10:29 A.M. 12:8-15. For example, when asked how many TVT-S products he has revised or explanted, he testified he does not know and "would be guessing." Flynn 3/24/16 10:29 A.M. 13:11-17. A reliable methodology does not involve "guessing."

In fact, on many of these issues, Dr. Flynn would not have to guess. Dr. Flynn testified that, in 2004, he started keeping a caselog that identified which products he implanted. Yet, Dr. Flynn repeatedly refused to produce the data or a summary of that data. Hence, neither Plaintiffs nor the Court can test whether Dr. Flynn is reliably "guessing" about his personal experience.

In 2013, Dr. Flynn also published an article discussing his personal experience with surgical management of mesh related complications. Flynn 4/19/16 101:4-25. In this publication, Dr. Flynn stated that he has seen an "alarming increase" and an "escalation in the severity" of mesh complications which has required adopting "an increasingly complex and aggressive approach to these healing abnormalities." Flynn 4/14/16 11:52 A.M. 144:3-145:13. When asked why he did not discuss his published observations in his reports here, he attempted to explain that his paper, titled, "The Use of Surgical Mesh for Incontinence and Prolapse Surgery: Indications for Use, Technical Considerations and Management of Complications" was not relevant to his reports and opinions at issue here. *Id.* at 145:14-146:1.

To the extent Dr. Flynn's opinions rely on his own "personal experiences," they should be excluded. Dr. Flynn cannot even remember which TVT product he started using first. He does not how many products he has actually implanted (although that information is available in

his undisclosed caselog). He does not know how many of his patients experienced complications – but was willing to guess that it was less than 5% (despite admitting that all were lost to follow-up after one year). Dr. Flynn does have some data available in his caselog, but he did not review that caselog for his expert reports and refused to produce even a redacted version of that caselog. Dr. Flynn's non-scientific beliefs, guesses and impressions do not form the proper foundation for an expert opinion and should be excluded. This is particularly true when the data that may prove or disprove his guesses is intentionally withheld.

In sum, all of Dr. Flynn's opinions rely either on his review of the scientific literature and his personal experience. As shown above, Dr. Flynn's review of the scientific literature was methodologically unreliable. He failed to find, let alone discuss, the most relevant and up-to-date literature. He admitted that, for the literature he did discuss, he cherry picked studies that supported his opinions and ignored those that provided contrary evidence. When confronted with solid science that contradicted his predetermined opinions, he became more entrenched in his unsupported opinions and refused to even attempt to distinguish the opposing science.

Moreover, Dr. Flynn's personal experiences are a similarly unreliable basis for his opinions. He cannot even recall when he started using any particular device. We do know that he stopped using the TVT-O because it was inferior to another device – yet, inexplicably he still maintains the TVT-O is an appropriate product to implant. The data to test his "personal experience" likely exists in the form of his "caselog;" yet, Dr. Flynn repeatedly refused to produce his caselog. It would be inappropriate to allow Dr. Flynn to testify based on beliefs and guesses about his personal experiences when data exists to test those experiences.

Dr. Flynn's expert opinions are all based on these two foundational predicates – scientific literature review and personal experience. Dr. Flynn failed to employ reliable scientific methods

when making his literature review or when reporting on his personal experience. Accordingly, Dr. Flynn should be excluded from offering expert opinions regarding these products.

II. DR. FLYNN IS NOT QUALIFIED TO OFFER OPINIONS ABOUT DEGRADATION, MANUFACTURING PROCESSES AND THE IFU, AND THESE OPINIONS SHOULD BE EXCLUDED.

As noted above, Dr. Flynn has failed to use any reliable methods in reaching his opinions that Ethicon's devices are safe and effective. However, should the Court permit Dr. Flynn to testify on these general opinions, the Court should exclude Dr. Flynn from offering opinions about the characteristics and pathology of polypropylene mesh, the design and manufacturing processes of Ethicon, and the sufficiency of warnings provided by Ethicon in the IFU and patient brochures. Dr. Flynn admitted he is not an expert in these areas and his review of the relevant evidence suffers from the same flaws discussed above.

A. Dr. Flynn's Opinions Regarding Design of the Mesh and Degradation Are Unsupported and Contrary to the Relevant Evidence Which He Has Admitted He Did Not Review.

In all of his reports, Dr. Flynn opines that the polypropylene mesh does not degrade in vivo. *See, e.g.*, TVT Report at 45 ("TVT mesh does not degrade."). He then backtracks and states that even if it does degrade, the literature fails to show that there is a clinically significant effect. However, Dr. Flynn has admitted he is not qualified to offer an expert opinion on mesh degradation and he failed to review the relevant scientific literature regarding degradation.

Dr. Flynn has admitted that he is not an expert in pathology: "[Y]ou're not a pathologist or an expert in pathology, correct? A: Correct." Flynn 10/30/14 139: 7-10 (attached as Exhibit L). He also admitted that he has never done any lab work, bench testing or biomechanical scientific research on these products. Flynn 8/29/14 9:15-17 (attached as Exhibit M). Dr. Flynn admitted that he has never looked at any explants under electron microscopy, which is the

accepted method to evaluate microscopic degradation. Flynn 4/19/16 66:4-7. Similarly, he testified that his pathology department does not use the electron microscopy equipment to evaluate explants. *Id.* at 72:21-73:6.

Moreover, when discussing whether infection was related to the mesh weave, he testified: "whether that is related to the designs of the meshes, that's something a materials scientist might know. But I'm not familiar with that." *Id.* at 9:22-25. Additionally, he testified that he has not reviewed the Ethicon design files and admitted he is not even aware of what a design file is. Flynn 4/14/16 11:52 A.M. 98:3-99:6.

In his reports, Dr. Flynn states that he has "never read or seen a single peer-reviewed published article or seen any cited by plaintiffs' experts that showed any clinical effect of degradation." *See, e.g.,* TVT Report at 27; Flynn 4/19/16 75:25-76:7. In deposition, Dr. Flynn then admitted that he had never read any of Dr. Iakovlev's papers, including one specifically addressing the clinical impact of mesh degradation. In that article, Dr. Iakovlev concludes, "Cracking of the degraded material indicated a contribution to clinically important mesh stiffening and deformation." Flynn 4/19/16 77:4-17. Dr. Flynn was unable to offer any criticisms of Dr. Iakovlev's study or its conclusions. When asked whether he would have liked to have read the Dr. Iakovlev article prior to reaching his opinion, he responded in his entrenched fashion: "I believe I've read enough articles on degradation. I've read enough systematic reviews and meta-analyses to feel confident in my opinion." *Id.* at 75:25-76:7.

When asked whether the microscopic cracking that has been identified in various articles can potentiate bacterial colonization in the mesh, Dr. Flynn admitted, "I'm uncertain on what the implications of the cracking would be. … I don't know one way or another." *Id.* at 79:8-22. However, Dr. Flynn admits that in one of his publications, he has concluded that bacterial

colonization of mesh "occurs frequently, and bacterial infection may account for pelvic pain in patients with painful mesh and dyspareunia." *Id.* at 82:3-10.

Dr. Flynn does discuss his concerns with certain articles that actually used a spectron microscope to evaluate degradation. However, Dr. Flynn admitted that he had never reviewed the Dr. Tzartzeva study, which addressed his very concerns with the methods for assessing degradation. *Id.* at 84:19-85:22. Using electron microscopy, the Tzartzeva study concluded that explant samples showed "extensive surface degradation with formation of microscopic surface cracks of several microns in length and depth" as compared to controlled pristine samples. *Id.*

Dr. Flynn is clearly offering opinions far beyond his expertise and experience regarding mesh design, degradation and pathology. He previously admitted he was not an expert in these fields and failed to review most of the relevant literature. Dr. Flynn's opinions regarding degradation, pathology and mesh design should be excluded.

B. Dr. Flynn's Analysis of Laser Cut Mesh (LCM) Is Unsupported and Unreliable.

In his reports, Dr. Flynn opines that there is "no difference in laser-cut versus mechanically cut mesh." TVT Report at 21. However, in an earlier deposition, Dr. Flynn admitted he was not an expert with regard to this very topic. He testified as follows: "I'm not a materials science expert…. [Others can] speak to the biomechanical data, if there's any differences [between laser and mechanically cut mesh]." Flynn 1/7/15 65:1-8 (attached as Exhibit N). Despite this earlier admission, Dr. Flynn now purports to be just such an expert. However, once again, the bases for his opinions lack any reliable scientific method.

To support his opinion that there is no difference between laser and mechanically cut mesh, Dr. Flynn relies upon his review of the scientific literature. When asked for the specific papers that compare laser and mechanically cut mesh, Dr. Flynn was compelled to admit he had

never seen such a paper. Flynn 4/19/16 123:13-19. Instead, Dr. Flynn claimed to be able to discern there was no difference simply because there appeared to be no difference in the outcomes reported in the studies before laser cut mesh was available compared to studies published after laser cut mesh became available. TVT Report at 21. Yet, he could not identify which mesh was used in any specific study, as such information is not available. Flynn 4/19/16 118:13-119:18. Instead, he assumed that all studies after 2006 used only laser cut mesh.

During his deposition, Dr. Flynn was confronted with an internal Ethicon email stating that, even after the launch of laser cut, 90 percent of the TVT and TVT-O products on the market were still mechanically cut. Dr. Flynn admitted, "That's what it says, and that may be true…" Flynn 4/19/16 120:23-121:13. Hence, even in later studies, the majority of products likely were mechanically cut, undermining the entire factual basis for Dr. Flynn's "literature review."

Faced with this reality, Dr. Flynn fell back on his "personal experience." Here, Dr. Flynn insisted that, in his practice, he did not experience any substantial difference between laser and mechanically cut mesh. Yet, Dr. Flynn admitted that he had no idea how many of the TVT devices he implanted were laser cut. Instead, he had to do a "rough calculation" in his head. Flynn 4/19/16 136:7-8. According to Dr. Flynn, even his undisclosed caselog does not identify whether the products he used were laser cut or mechanically cut. Flynn 4/19/16 156:23-157-1.

Experts cannot base their opinions on unsupported presumptions. *Hathaway v. Bazany*, 507 F.3d 312, 318 (5th Cir. 2007). Dr. Flynn's "rough calculations" are not a proxy for sound scientific evidence. Dr. Flynn's opinions regarding laser cut mesh should be excluded.

C. Dr. Flynn Has No Reliable Basis for His Opinions Regarding the Adequacy of Ethicon's Warnings.

Dr. Flynn opines that the IFUs and patient brochures are adequate. However, Dr. Flynn has admitted he is not an FDA expert. Flynn 8/29/14 17:13-14 ("You don't consider yourself an

FDA expert? A: No certainly not."). When asked whether he knows what FDA regulations govern the IFU warnings, he responded, "I'm familiar with FDA requirements; I am by no means an expert in FDA regulatory…" Flynn 4/19/16 33:11-12. Dr. Flynn has never been involved in writing or preparing a warning for a medical device. Flynn 4/14/16 11:52 A.M. 73:11-17. Likewise, Dr. Flynn has not reviewed Ethicon's internal standards governing requirements for warnings. In fact, Dr. Flynn does not know whether Ethicon has any standards governing requirements for warnings. Flynn 4/14/16 11:52 A.M. 77:2-17.

Because Dr. Flynn has no experience writing labels and does not know the applicable standards, his opinions are simply based on his own subjective, personal belief. However, Dr. Flynn cannot even reliably apply his own subjective personal standard. When asked what warnings he expects in an IFU, he testified that he expects a warning to include "complications that might be unique to that product that's not part of ordinary urogynecologic practice…" *Id.* at 74:1-8. However, he later inconsistently testified that he would want to know about the risk of damage to surrounding structures like the bladder, urethra, bowel, nerves, or blood vessels. *Id.* at 79:15-19. Dr. Flynn admitted that damage to surrounding structures and organs is not a risk that is unique to Prolift. However, he would still want those risks to be included in the label. *Id.* at 79:15-81:1. Dr. Flynn contradicts his own subjective standard and demonstrates that he has not reached his opinions regarding warnings through any reliable methodology.

Moreover, Dr. Flynn has not actually reviewed the relevant evidence to reliably reach his opinions. In his various reports, he offers opinions that *all* the IFUs, are "adequate." *See, e.g.*, TVT-R Report at 45. In 2015 Ethicon updated the TVT and TVT-O IFUs to include additional, stronger warnings. *See, e.g.*, 2015 TVT-O IFU (with redline changes) (attached as Exhibit O). However, Dr. Flynn testified that he is unsure whether he reviewed the 2015 updated IFUs for

the TVT products. Flynn 4/19/16 113:12-19. It is methodologically impossible for Dr. Flynn to reliably opine that the warnings are sufficient, if Ethicon later strengthened the warnings and he never reviewed the updated stronger warnings. Dr. Flynn's opinions regarding the warnings in the IFUs must be excluded because the opinions are not "based on sufficient facts or data" and are not "the product of reliable principles and methods." *See* Fed. R. Evid. 702.

D. Dr. Flynn's Impermissible Legal Conclusions Must Be Excluded.

The Court has repeatedly held that experts may not draw legal conclusions. *See, e.g., In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 629 (S.D. W.Va. 2013). Dr. Flynn has offered numerous legal conclusions such as "…Ethicon has properly warned physicians of the adverse events…" TVT Report at 30. All of Dr. Flynn's legal conclusions must be excluded.

CONCLUSION

Dr. Flynn's reports are the product of litigation-driven methodology. He failed to perform a systematic review of the literature, ignored the most relevant literature, and intentionally cherry picked studies that supported his opinions. His personal experience is filled with "guesses," "beliefs," and "rough calculations" – not scientific rigor and analysis. Finally he admits he is unqualified to express opinions regarding pathology, biomaterials, product design and warnings. Dr. Flynn's testimony should be excluded.

/s/ Joseph J. Zonies
Joseph J. Zonies, Esq.
Reilly Pozner LLP
1900 Sixteenth Street, 17th Floor
Denver, Colorado 80202
(303) 893-6100
(303) 893-6110 fax
jzonies@rplaw.com

/s/ Thomas P. Cartmell
Thomas P. Cartmell, Esq.
Jeffrey M. Kuntz, Esq.
Wagstaff & Cartmell LLP
4740 Grand Avenue, Suite 300
Kansas City, MO 64112
816-701-1102
Fax 816-531-2372
tcartmell@wcllp.com
jkuntz@wcllp.com

/s/ D. Renee Baggett
Bryan F. Aylstock, Esq.
Renee Baggett, Esq.
Aylstock, Witkin, Kreis and Overholtz, PLC
17 East Main Street, Suite 200
Pensacola, Florida 32563
(850) 202-1010
(850) 916-7449 (fax)
rbaggett@awkolaw.com
baylstock@awkolaw.com

CERTIFICATE OF SERVICE

I hereby certify that I filed the foregoing **PLAINTIFFS' MOTION TO EXCLUDE THE GENERAL CAUSATION OPINIONS AND TESTIMONY OF BRIAN FLYNN, M.D.** on May 5, 2016, using the Court's CM/ECF filing system, thereby sending notice of said filing to all counsel.

/s/ Sarah Peasley
Sarah Peasley